REMARKS

FORMAL MATTERS:

Claims 1, 5-7, 12, 13, 15-17 and 19 are pending after entry of the amendments set forth herein.

Claims 2-4, 8-11, 14 and 18 are canceled without prejudice.

Claim 19 has been added. Support for new claim 19 can be found at page 33, lines 23-27.

Claims 1, 5, 6, 7, 12 and 17 are amended. Support for these amendments is found throughout the specification such as at page 16, line 12; page 33, lines 28-34, original claim 3; page 32, line 33 to page 33, line 17; page 36, lines 29-35; and in original claim 8.

No new matter has been added.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1, 3 and 5 have been rejected under 35 U.S.C. §112, first paragraph, asserting that the specification "does not reasonably provide enablement for a method for evaluating renal functions"

The rejection is believed to have been overcome in that the phrase "evaluating renal functions" of claims 1 and 5 has been replaced with "diagnosing mesangial cell proliferative nephropathy". Based on this amendment, the phrase "renal functions" of claims 6 and 7 has been replaced with "mesangial cell proliferative nephropathy", and claim 19 has been added, which limits the nephropathy to IgA nephropathy or minimal-change nephritic syndrome. Support for these amendments can be found in the original specification. No new matter has been introduced. The rejection to claim 3 is now moot as it has been cancelled as mentioned above.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1, 3 and 5-18 were rejected under 35 U.S.C. §112, second paragraph, "for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention". Claims 3, 8-11, 14 and 18 are not discussed as the have been cancelled.

Claim 1 stands rejected for allegedly failing to clarify how determining the amount of megsin protein correlates to renal function.

By the above-mentioned amendment of replacing "evaluating renal functions" with "diagnosing mesangial cell proliferative nephropathy", the method of claim 1 is now a method for diagnosing mesangial cell proliferative nephropathy. Step (e) "*diagnosing mesangial cell proliferative nephropathy when said amount of bound megsin protein is higher than the control sample*" has been added to show how determining the amount of megsin protein in step (d) correlates to diagnosing mesangial cell proliferative nephropathy.

Claim 1 also stands rejected because the word "said sample" of claim 1(b) is allegedly vague and indefinite.

The words "biological specimen" of claim 1(a) and "specimen" of claim 1(d) have been replaced with "urine sample".

Claims 6 and 12 stand rejected as allegedly being vague and indefinite due to the expression "against" in the expression "antibody against the amino acid sequence of . . .". The objected to expression "against" has been replaced with the underlined phrase "antibody that recognizes a polypeptide consiting of the amino acid sequence of . . .".

Claim 12 stands rejected for failing to clarify which antibody is bound to the antigen, and for being unclear as to whether the "antigen" is that in the preamble or whether it is SEQ ID:11, 12, 14 or 17.

Claim 12 has been amended to overcome the rejection.

Rejections under 35 U.S.C. §102

The Examiner rejects claims 6 and 7 under 35 U.S.C. §102 as being anticipated by Tsujimoto et al. (J.B.C. vol. 274, no. 24, 15373-15380, 1997). The claims have been amended so they are directed to the epitopes of the first and second antibodies and specifically to the amino acid sequences of SEQ ID NOS:12 and 11, respectively. Thus, the rejection is believed to have been overcome.

Rejections under 35 U.S.C. §103

Claims 6-9 and 11-18 were rejected under 35 U.S.C. §103 as being unpatentable over Gombinski (USP 6,297,062) in view of Tsujimoto et al. Claims 6-11 were rejected as being unpatentable over Rohr (USP 5,445,970) in view of Tsujimoto et al.

These references disclose a general immunoassay method using magnetic granules for the solid phase. In contrast, the present invention (Example 10, page 36, lines 17-28) uses magnetic granules conjugated with rabbit polyclonal anti-megsin peptide-2 antibodies for the solid phase, and rabbit polyclonal anti-megsin peptide-1 antibodies for labeling.

Claims 8-11 have been canceled.

Claims 6, 7, 12 and 17 have been amended so that each of the solid phase antibodies and liquid phase antibodies is limited to an antibody that recognizes a specific amino acid sequence. The solid phase has been restricted to granules. Megsin in an *unconcentrated urine* sample can be directly detected using these granules.

The cited references neither disclose nor teach that megsin in *unconcentrated urine* can be detected using granules and specific combinations of the antibodies. The combined use of granules and antibodies allows megsin protein to be detected with sufficient sensitivity, and at the same time, eliminates the necessity of concentrating urine samples and demonstrating improved unexpected results of the present invention.

If granules are not used, as in Example 7 of the present invention where ELISA plate was used as the solid phase, the urine sample to be tested would have to be concentrated in advance. In sum, the feature of using granules in combination with megsin protein-specific antibodies and the convenient detection of urine samples is a feature which demonstrates the improved results obtained and distinguishes the claimed invention from the cited prior art.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SHIM-012.

Respectfully submitted,
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Date: 27/DEC/04

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